

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
(Attorney Docket No. C1190/20009)

First Named Inventor:	)	
Laurent Di Constanzo	)	Confirmation No. 7903
	)	
Serial No.: 09/914,544	)	Before the Examiner:
	)	Oh, Simon J.
Filed: March 19th, 2002	)	
	)	
For: Orally Dispersable	)	Art Unit: 1618
Tablet with Low Friability	)	
and Method for Preparing	)	
Same	)	

**DECLARATION UNDER RULE 132**

To Honorable Commissioner of Patents and Trademarks  
Washington, D.C.

Sir :

I, Edouard Gendrot, of 24 rue de Dreux, 28500,  
GARNAY, FRANCE do solemnly declare :

THAT I have been working with ETHYPHARM S.A. since  
**May 2<sup>nd</sup>, 1990** and that I now hold the position of  
**Production Manager;**

THAT, I am a named inventor on the present patent  
application n° 09/914,544, and that I am fully familiar  
therewith ;

THAT, I have read and understood the Office Action  
of April 12, 2007 in connection with the present patent  
application ;

THAT, I have read and understood Hunter et al. (US 6,391,337), Schmitz et al. (US 6,079,968) and Valentine (US 4,684,534) ;

THAT, the experiments described in the attached test report were carried out under my supervision;

THAT, the directly compressible tablets were prepared using coated paracetamol as the active ingredient, direct compressed mannitol and crystalline powder mannitol as the soluble agent, crospovidone as the disintegrating agent, a sweetener, a flavour, and magnesium stearate as the lubricating agent;

THAT, the tablets of Hunter et al. are coated and thus not susceptible to friability when removed from the blisters in which they are packed, in contrast to the directly compressible tablets of the present patent application;

THAT, tablets of the present patent application were prepared by applying the lubricating agent (i.e. magnesium stearate) on the external surface of the punches;

THAT, due to the application of the lubricating agent on the surface of the tablet, the friability of the tablets of the present patent application is less than 1%;

THAT, the disintegration time of the tablets of the present patent application is not negatively affected by the application of the lubricating agent on the external surface of the tablets, on the contrary the

disintegration time is in fact increased by such an application;

I, the undersigned, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and, further, that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18, of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

13 July 2007



Edouard Gendrot

REQU LE

16 AOUT 2007

SERV JURIDIQUE